

# Comparison study of treatment given to children with asthma by a nurse practitioner, a general practitioner or a pediatrician. (Vergelijkende studie met betrekking tot de controle van kinderen met astma door de nurse practitioner, de huisarts of de kinderarts)

<b>Submission date</b> 11/08/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/08/2011	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Maarten Kuethe

**Contact details**  
Department of Pediatrics  
Amphia hospital  
PO Box 90157  
Breda  
Netherlands  
4800 RL

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Comparison study to follow-up of treatment given to children with stable asthma by a nurse practitioner, a general practitioner or a pediatrician: a randomized controlled trial

### Acronym

TRAM

### Study objectives

TRAM (TRAns mural Asthma Management). Treatment of children with stable asthma by a nurse practitioner is not inferior to treatment by a general practitioner or a pediatrician.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

TWOR Medical Centre "Rijnmond" South, Rotterdam approved on 11 January 2008, ref: nl.17972.101.07

### Study design

Randomized controlled trial

### Primary study design

Observational

### Secondary study design

Randomised controlled trial

### Study setting(s)

GP practice

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Pediatric asthma

### Interventions

Children were randomly assigned to one of the three follow up arm and at baseline, one year & two year a variety of outcome measures were collected.

1. Management by general practitioner
2. Management by paediatrician
3. Management by asthma nurse

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Inhaled corticosteroid (beta-2-agonist), PD20 methacholine

### **Primary outcome measure**

1. Airway hyper responsiveness
  2. PD20 methacholine
- Measured at baseline, one year & two year

### **Secondary outcome measures**

1. Forced expiratory volume in one second (FEV1) before and after bronchus dilatation with beta-2-agonist
2. Exhaled nitric oxide (NO)
3. Asthma Control Questionnaire
4. Health economics
5. Prescribed medication
6. Quality of Care assessment by completing the QUOTE-CNSLD instrument by parents
7. Completion of Likert scale by the children

### **Overall study start date**

04/03/2005

### **Completion date**

28/01/2009

## **Eligibility**

### **Key inclusion criteria**

1. Children 6-16 years
2. Moderate asthma as defined by the guideline of the dutch pediatric pulmonologists or diagnosed as asthma by their general practitioner (GP) and on prophylactic treatment with inhaled corticosteroid (ICS)

### **Participant type(s)**

Patient

### **Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

110

**Key exclusion criteria**

Serious, poorly controlled asthma requiring step intravenous (IV) treatment according to the action plan in the guideline

**Date of first enrolment**

04/03/2005

**Date of final enrolment**

28/01/2009

**Locations****Countries of recruitment**

Netherlands

**Study participating centre****Department of Pediatrics**

Breda

Netherlands

4800 RL

**Sponsor information****Organisation**

Amphia Hospital (Netherlands)

**Sponsor details**

Langendijk 75

Breda

Netherlands

4819 EV

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.amphia.nl/Pages/default.aspx>

**ROR**

<https://ror.org/01g21pa45>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Amphia Hospital (Netherlands)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration